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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,890	02/04/2004	Jeffrey Gabbay	082871-000700US	5373
20350 7590 06/19/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER HANDY, NIKKI R	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 06/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/772,890	<b>Applicant(s)</b> GABBAY, JEFFREY	
	<b>Examiner</b> Nikki Handy	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 10-27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9, 28 and 30-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of Claims**

**Claims 5-9, 28, and 30-37 are pending.** Claims 1-4, 11, 13, 16, 20, 22, 24, 26 and 27 have been canceled. Claims 10, 12, 14, 15, 17, 18, 19, 21, 23, 25 and 29 are withdrawn. Receipt of Applicant's amended claims and remarks/arguments filed on October 6, 2006 are acknowledged.

The rejection of Claims 4-9, 27 and 28 under 35 U.S.C. 102(b) as being anticipated by Jacobson et al. (U.S. Patent 5,180,585) is withdrawn because the applicant's arguments are persuasive.

### **Response to Restriction Requirement**

It should also be noted that the applicant has requested reconsideration and withdrawal of the Restriction Requirement of Claim 29. The traversal is on the ground(s) that there would not be undue burden in examining product Claim 29. The traversal has not been found persuasive. The examiner cites that the prior art search required for each respective component would be divergent, thereby causing an undue burden.

### **Statutory Double Patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 5, 6, 8 and 28 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 5, 6, 8, 15, 19, 20, 23, 27, 30 and 31 of prior U.S. Patent No. 7,169, 402 B2. This is a double patenting rejection.

#### **Provisional Nonstatutory Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 6, 8, and 28 are rejected for "obviousness-type" double patenting over conflicting claims 1, 2, 5, 6 and 8 of copending application serial no. 11/648,858.

More specifically Claims 5, 6, 8, 19 and 28 of the instant application are directed to an antiviral hydrophilic polymeric material in the form of a film comprising: a hydrophilic polymer selected from the group consisting of polyvinylalcohol, acrylic, nitrile, "silastic rubber" or latex; and a cationic copper powder mixture of water insoluble particles of divalent copper cations  $\text{Cu}^{++}$  and univalent copper cations  $\text{Cu}^{+}$ ; wherein said water insoluble particles are from about 1  $\mu\text{m}$  to about 10  $\mu\text{m}$  in diameter and are encapsulated within said hydrophilic polymer in an amount from about 1 wt. % to about 3 wt. %.

Claims 1, 2, 5, 6, and 8 of the conflicting copending application serial no. 11/648,858 are directed to an antimicrobial and antiviral polymeric material, having

microscopic particles of ionic copper encapsulated therein and protruding from surfaces where the polymeric material is a film. The size of the particles are between 1 and 10 microns. The particles are in the amount between 0.25 and 10% of the polymer weight. Furthermore, a condom comprises an antiviral polymeric material, having microscopic particles of ionic copper.

As a result, although claims 5, 6, 8 and 28 of the instant application are not identical to claims 1, 2, 5, 6 and 8 of the conflicting copending application serial no. 11/648,858, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope as discussed hereinabove. This is a provisional non-statutory double patenting rejection since the conflicting claims have not yet been patented.

Claims 5-7 and 28 are rejected for "obviousness-type" double patenting over conflicting claims 1-4 of copending U.S. Pre-Grant Patent Application Publication 2004/0247653 (hereinafter the conflicting Gabbay '653 publication).

More specifically, claims 5-7 and 28 of the instant application are directed to an antiviral hydrophilic polymeric material in the form of a film comprising: a hydrophilic polymer selected from the group consisting of polyvinylalcohol, acrylic, nitrile, "silastic rubber" or latex; and a cationic copper powder mixture of water insoluble particles of divalent copper cations  $\text{Cu}^{++}$  and univalent copper cations  $\text{Cu}^{+}$ ; wherein said water insoluble particles are from about 1  $\mu\text{m}$  to about 10  $\mu\text{m}$  in diameter and are encapsulated within said hydrophilic polymer in an amount from about 1 wt. % to about 3 wt. %.

Claims 1-4 of the conflicting Gabbay '653 publication are directed to an antimicrobial and antiviral polymeric material in the form of a sheet comprising: a polymer selected from the group consisting of polyamide, polyalkylene, polyester and acrylic; and a cationic copper powder mixture of water insoluble particles of divalent copper cations  $\text{Cu}^{++}$  (released from a cupric oxide or  $\text{CuO}$ ) and a univalent copper cations  $\text{Cu}^+$  (released from cuprous oxide or  $\text{Cu}_2\text{O}$ ); wherein said water insoluble particles are from about 1  $\mu\text{m}$  to about 10  $\mu\text{m}$  in diameter and are embedded within said polymer in an amount from about 0.25 wt. % to about 10 wt. %.

As a result, although claims 5-7 and 28 of the instant application are not identical to claims 1-4 of the conflicting Gabbay '653 publication, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope as discussed hereinabove. This is a provisional non-statutory double patenting rejection since the conflicting claims have not yet been patented.

Because neither the instant application and '653 are in condition for allowance, this rejection has been made provisionally and the applicant has not filed a terminal disclaimer.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 5-9, 28 and 30-37 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inactivation of the Herpes Simplex Virus Type 1, does not reasonably provide enablement for the inactivation of all viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) The nature of the invention.
- 2) The state of the prior art.
- 3) The existence of working examples.
- 4) The breadth of claims.
- 5) The amount of direction and guidance provided by the inventor.
- 6) The predictability of the art.
- 7) The relative skill of those in the art.
- 8) The quantity of experimentation necessary.



1) Nature of the invention.

The nature of the invention relates to a multi-layered hydrophilic polymeric material for the inactivation of a virus where copper oxide particles release both  $\text{Cu}^{++}$  or  $\text{Cu}^+$ .

2) State of the prior art.

The state of the prior art suggests that there is no means of inactivating a virus using a multi-layered hydrophilic polymeric material. Jones et al. teach copper (cupric oxide) in the treatment of influenza virus infection. See Jones et al. (U.S. Patent No. 6,107,281, Column 4, lines 6, 15 and 16).

3) Existence of working examples.

Working examples can be found on pages 15-18 where applicant teaches the inactivation of HIV-1 type virus and HSV-1 type virus. Example 2 demonstrates the effects of Cupron copper-containing latex bags and its ability to deactivate the virus. The observations of the studies suggest a device is effective for inactivating viruses in fluids brought in contact therewith and thus e.g. blood storage bags can assure that blood stored therein will not transmit a virus to a recipient of said blood.

4) Breadth of claims.

The claims are directed to the inactivation of a virus using a multi-layered hydrophilic polymeric material where copper oxide particles release both  $\text{Cu}^{++}$  or  $\text{Cu}^+$ . The inactivation of a virus encompasses all viruses. Hence the claims are broad.

5) Amount of direction and guidance provided by the inventor.

The amount of direction or guidance present is found in the specification on page 16 wherein studies were performed using aliquots of medium containing HIV in sterile Cupron copper-containing latex bags to demonstrate the inactivation of HIV. The data present does not show support for the inactivation of HIV. Hence there is no guidance provided for the inactivation of HIV or all viruses.

6) The predictability of the art.

There is no known treatment for the inactivation of all viruses, therefore the ability to inactivate all viruses is highly suspect.

The essential element required for the validation of a preventive therapeutic is the ability to test the subjects under conditions that would be suitable humans. In view of the teachings above, and the lack of guidance and/or exemplification in the specification, it is not believable that the inactivation of a virus can be achieved.

**Objection to Claims**

Claim 25 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 23. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### **Telephonic Inquiry**

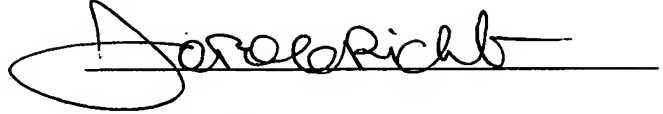
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki Handy whose telephone number is (571) 272-9923. The examiner can normally be reached on Monday-Friday 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nikki Handy  
Patent Examiner  
Art Unit 1616

A handwritten signature in black ink, appearing to read "Johann Richter", is written over a horizontal line. The signature is stylized with a large, looped initial "J" and a long horizontal stroke at the end.

Johann Richter  
Supervisory Patent Examiner  
Technology